REMARKS

By the foregoing amendments, claims 77, 78, 80-84 and 114-116 are pending in this application. Claims 1-76, 79 and 85-113 have been canceled without prejudice or disclaimer. Claims 80-82 have been withdrawn as not elected in response to the restriction requirement mailed November 14, 2007. Applicant reserves the right to pursue this subject matter in one or more divisional applications.

Independent claim 77 has been amended to recite the feature of now-canceled claim 79, namely the expression product being an RNA, and to replace "the step of assaying" with "a step of assaying". Dependent claims 80 and 83 have been amended to reflect updated claim dependency.

New claim 114 has been added to recite that the step of assaying is preceded by a step of enriching RNA. Support for claim 114 can be found in the Specification as originally filed in, e.g., claim 13 and page 9 at lines 4-26.

New claim 115 has been added to recite that the expression product is detected using PCR, SDA, SSSR, LCR, TMA or NASBA, with the complete names of the methods included. Support for claim 115 can be found in the Specification as originally filed in, e.g., claim 14, page 10 at lines 11-12, and page 67 at lines 24-27.

New claim 116 has been added to recite that the expression product is detected using RT-PCR. Support for claim 116 can be found in the Specification as originally filed in, e.g., claim 15, page 10 at lines 12-14, and page 67 at lines 24-27.

Amendments of the claims are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record.

Applicant expressly reserves the right to file one or more continuing applications hereof containing the canceled or unamended claims.

The Specification has been amended herein to correct an obvious error. The correct word can be inferred from the paragraph as filed.

The claim and specification amendments add no new matter, and their entry is respectfully requested.

The Rejection under 35 U.S.C. § 112, ¶ 1 (Enablement)

Claims 77, 78 and 83-87 have been rejected solely under 35 U.S.C. § 112 ¶ 1 as lacking enablement. Claim 79 was marked as "rejected" in the Office Action Summary, although this claim was not mentioned in the Detailed Action. Based on the content of the Detailed Action, Applicant assumes that claim 79 was also rejected solely under 35 U.S.C. § 112 ¶ 1 as lacking enablement. In particular, the Office Action states:

> "...., the specification does not provide guidance on how to assay for RNA in blood samples. Furthermore, the specification only contains data for at least 150% elevated RNA level in prostate cells but not blood cells. Neither does the specification show whether the level of mRNA expression is correlated to the level of protein expression in blood and prostate cells.
>
> It is known in the art that expression levels of mRNA and protein by cell types exhibit a range of correlations for different genes...." Office Action at page 4.

To advance prosecution, claims 79 and 85-87 have been cancelled. Independent claim 77 has been amended to recite the feature of now-canceled claim 79. Applicant respectfully traverses the rejection of claims 77, 78, 83 and 84 which, as amended, are all directed to RNA as the expression product.

The enablement requirement sets forth that the specification must describe how to make and use the claimed invention. 35 U.S.C. § 112 ¶ 1. To satisfy the enablement requirement, the

specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention needs to be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991).

In order to make an enablement rejection, the Patent Office has the initial burden to establish a reasonable basis to question why the scope of protection provided by a claim is not adequately enabled by the disclosure. *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993). It is incumbent upon the Patent Office to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure. *In re Marzocchi*, 439 F.2d 220 (CCPA 1971).

Claim 77 as amended recites a method of screening for early stage prostate cancer, the method comprising a step of assaying, in a patient sample, an expression product of a HML-2 retrovirus, wherein an increased level of said expression product of at least 150% relative to a control sample level indicates that the patient should undergo further testing for the presence of prostate cancer, wherein the patient sample is a prostate or blood sample, wherein the expression product is an RNA, and wherein the HML-2 retrovirus is HERV-K(CH) (emphases added).

The Office Action asserts that "the specification does not provide guidance on how to assay for RNA in blood samples". Applicant respectfully disagrees.

The Specification as filed teaches example methods of detecting HML-2 encoded mRNA expression products either directly (page 9, line 27 to page 10, line 14) or indirectly (page 10,

lines 15-22). The Specification also teaches hybridization conditions for an example method of directly detecting mRNA at page 12, lines 13-30. The Specification further teaches how to detect an increased level of HML-2 retrovirus encoded expression product in a patient prostate or blood sample relative to a negative control sample at page 24, line 7 to page 25, line 16. These teachings of the Specification are sufficient to enable the claimed methods with respect to assaying RNA in a patient prostate or blood sample.

In addition, Applicant respectfully submits that, at the time of the claimed invention, it was well known in the art how to assay for RNA in blood samples. See, e.g., Slade et al. (Journal of Clinical Oncology 1999, 17:870-879, submitted herein) at page 871, Hoon et al. (Journal of Clinical Oncology 1995, 13:2109-2016, submitted herein) at pages 2110-2111, Yao et al. (Cancer Treatment and Research 1996, 88:77-91, submitted herein) at pages 84-88, and Andersson et al. (Aids Res. And Hum. Retroviruses 1996, 12:833-840, cited in the office action dated November 15, 2004) at pages 834-835. Therefore, it should be acceptable even to omit the description of how to assay for RNA in blood samples according. *In re Buchner* at 660, 661.

The Office Action asserts that the claims are not enabled because "the specification only contains data for at least 150% elevated RNA level in prostate cells but not blood cells". Applicant respectfully disagrees.

First of all, the Specification as filed disclosed that "the up-regulation relative to the control (100%) will usually be at least 150%" without limiting the up-regulation to prostate cells only (page 25, line 17-19). In addition, the Specification as filed teaches that the patient sample may be cells in blood or virions independent from prostate cells where the diagnostic method of the invention is based on HML 2 mRNA (page 2, line 27 to page 3, line 18).

Secondly, the Patent Office does not explain why it doubts that there can be at least 150% elevated HERV-K (CH) RNA level in blood cells in patients who may have early stage prostate cancer. The Patent Office also offers no evidence or reasoning why it doubts Applicant's disclosure that blood cells can be used in the invention recited in claim 77 as amended. *In re Marzocchi* at 224. The Patent Office did not show any reference that teaches a lack of correlation between RNA expression in blood cells and in prostate tissue or between HERV-K (CH) RNA expression in blood cells and prostate cancer. At best the four references cited by the Patent Office, Pascal et al., Guo et al., Chen et al., and Lichtinghagen et al., show differences in mRNA and protein expression levels in given cell types, but not cell-to-cell correlation of RNA expression levels such as between blood cells and prostate tissue.

Thirdly, claim 77 as amended does not suggest that an at least 150% increased level of HERV-K (CH) RNA expression in blood cells indicates that the patient definitely has prostate cancer, it only suggests that "the patient should undergo further testing for the presence of prostate cancer". Therefore, even if the percentage of increased level of HERV-K (CH) RNA expression in blood cells is not the same as that in prostate cells, an at least 150% increased level of HERV-K (CH) RNA expression in blood cells may still warrant further testing for the presence of prostate cancer.

In conclusion, Applicant respectfully submits that the Patent Office failed to establish a reasonable basis to question why the scope of protection provided by the claims as amended is not adequately enabled by the disclosure, and that the Patent Office failed to explain why it doubts the truth or accuracy of any statement in the current supporting disclosure or to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the

contested statement.

In view of the amendments and for at least the above reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, ¶ 1 is respectfully requested.

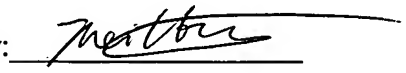
CONCLUSION

In view of the above amendments and remarks, all pending claims of this application are believed to be in condition for allowance. A written indication of the same is respectfully requested. This response is believed to completely address all of the substantive issues raised in the Office Action mailed March 4, 2009.

The Commissioner is hereby authorized to charge any fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 03-1664. This however is not an authorization to pay the issue fee.

Respectfully submitted,

Date: July 2, 2009

By: 

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